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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,853	02/11/2008	Sacha Gnjatich	NY-LUD 5826-US	7070
7590 Norman D Hanson Fulbright & Jaworski 666 Fifth Avenue New York, NY 10103				
09/30/2010				
EXAMINER				
DIBRINO, MARIANNE NMN				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/556,853

Applicant(s)

GNJATIC ET AL.

Examiner

MARIANNE DIBRINO

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/10/06, 6/30/08 & 9/9/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Continuation Sheet.
- Paper No(s)/Mail Date _____

Continuation of Attachment(s) 6). Other: Notice to Comply with the Sequence Requirements.

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, Applicant is required to provide SEQ ID NO for the sequences appearing in Table 1 of the specification. Note that where an actual sequence is depicted, it is not sufficient to provide a range of amino acid residues of a larger sequence; each sequence must have its own SEQ ID NO.

Also note that the footnote to Table 1 states that the amino acid positions referred to in said Table refer to the amino acid positions within SEQ ID NO: 1 of each NY-ESO-1 derived peptide. However, note that the sequences depicted in Table 1 are no subsequence of the protein sequence of SEQ ID NO: 1 that appears in the sequence listing in the instant application (see item #5 of this Office Action below).

Applicant is advised that for any response to be considered fully responsive said response has to be fully responsive to the sequence compliance requirements.

2. Applicant's amendments and responses filed 3/10/06, 6/30/08 and 9/9/10 are acknowledged and have been entered.

3. Applicant's election of Group I (claims 1-8), and species of peptide consisting of the amino acid sequence of amino acid residues 80-109 of SEQ ID NO: 1 in Applicant's amendment and response filed 9/9/10 is acknowledged.

Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP, 818.03(a)).

Claims 1-8 read on the elected species and are presently being examined.

4. The amendment filed 6/30/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of the parent applications. The amendment was not mentioned in the first executed declaration.

Applicant is required to cancel the new matter in the reply to this Office Action.

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5. The disclosure is objected to because of the following informalities: The amino acid sequences that appear in Table 1 that are listed as NY-ESO-1 peptides, amino acid residues 80-109, 87-98, 108-119 and 121-132 of SEQ ID NO: 1 are not subsequences of SEQ ID NO: 1 that appears in the sequence listing in this application. Specifically:

amino acid residues of SEQ ID NO: 1	As listed in Table 1
80-109 AAGPGSALLGPTLAMPPATPMGAGLAAASL	80-109 ARGPESRLLFEFLAMPFATPMEAEARRSL
87-98 LLGPTLAMPPAT	87-98 LLEFYLAMPFAT
108-119 SLAGAAPPLPVP	108-119 SLAQDAPPLPVP
121-132 VLLLGPTVSGAI	121-132 VLLKEFTVSGNI

In addition, Applicant is requested to check the remaining sequences in Table 1 to determine whether or not these sequences are subsequences of SEQ ID NO: 1.

Please note: the sequence listed as SEQ ID NO: 1 in the sequence listing of the instant application does not match the sequence of SEQ ID NO: 1 in the parent priority document 60/474,893, nor does it match the sequence for NY-ESO-1 in U.S. Patent No. 5,804,381 and Chen *et al* (PNAS USA 94: 1914-1918, 1997, the disclosures of which are incorporated by reference (see the paragraph spanning pages 2-3 of the instant specification and lines 10-15 on page 4).

Appropriate correction is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to make and/or use the instant invention, an isolated peptide and composition thereof, consisting of the amino acid sequence selected from the group consisting of amino acid residues 80-109, 87-98, 108-119 and 121-132, and including the limitations recited in the dependent claims.

The specification has not enabled the breadth of the claimed invention because the claims encompass peptide subsequences of a protein sequence SEQ ID NO: 1 in the sequence listing. However, the said sequence is not the sequence of NY-ESO-1, nor is the identity or use of the said sequence disclosed in the specification (see below). In addition with regard to making and using, the dependent claims recite limitations such

as: "useful in stimulating a CD4+ T cell response" (claim 2), "useful in stimulating a T cell response in a subject" (claim 3).

The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed peptide and composition thereof can be made and/or used.

The specification discloses that the sequence of NY-ESO-1 is disclosed in U.S. Patent No. 5,804,381 and Chen *et al* (PNAS USA 94: 1914-1918, 1997, the disclosures of which are incorporated by reference (see the paragraph spanning pages 2-3 of the instant specification and lines 10-15 on page 4).

However, a review of these aforementioned evidentiary references reveals that NY-ESO-1 protein has a different sequence than that listed as SEQ ID NO: 1 of the instant sequence listing (SEQ ID NO: 1 of U.S. Patent No. 5,804,381 and Figure 3 in Chen *et al*).

The specification does not disclose the identity of the protein sequence listed as SEQ ID NO: 1 in the sequence listing, nor that the peptide subsequences recited in instant claim 1 can stimulate a CD4+ T cell response, nor any T cell response, nor does it disclose any use for the protein or the peptide subsequences.

There is insufficient guidance in the specification as to how to use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See *In re Wands* 8 USPQ2d 1400 (CAFC 1988).

8. Claim 1 is objected to because of the following informality: A proper Markush group recites "and" before the last recited element in the group. The instant claim recites "or."

Appropriate correction is required.

9. Peptides consisting of amino acid residues 80-109, 87-98, 108-119 and 121-132 of the sequence of SEQ ID NO: 1 that is listed in the sequence listing of the instant application are free of the art.

Note that the sequences listed in Table 1 of the specification that are labeled "80-109", "87-98", "108-119" and "121-132" have not been searched.

They can not be searched until SEQ ID NO are provided, or a SEQ ID NO is provided for the protein of origin for these peptide subsequences.

10. No claim is allowed.

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11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/G.R. Ewoldt/
Primary Examiner, Art Unit 1644